



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/527,461

03/11/2005

John Peter Gilday

056291-5201

5299

9629 7590 02/13/2008
MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

02/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,461	Applicant(s) GILDAY ET AL.	
	Examiner REBECCA L. ANDERSON	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/8/05, 3/11/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 4-8 are currently pending in the instant application and are rejected.

Election/Restrictions

Applicant's election of Group I, claims 1 and 4-8 in the reply filed on 22 January 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology such as "said". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

Claims 1 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 has the phrase "with formic acid, or a reactive derivative thereof". The term "derivative" found in the claims can be defined as a compound, usually organic, obtained from another compound by a simple chemical process or an organic compound containing a structural radical similar to that from which it is derived. Therefore, the term "derivative" found in the claims renders the claims indefinite because it is unclear what compounds are being claimed as a reactive derivative of formic acid, i.e. what similar radical is encompassed by the instant claims. It is suggested that the phrase ",or a reactive derivative thereof" be deleted from claim 1 and claim 8 be made independent or claim 1 amended to include only those reactive derivatives supported by the specification on page 4 to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

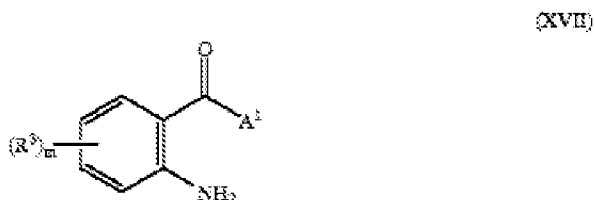
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

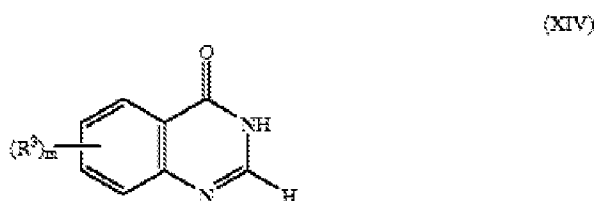
Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,294,532 in combination with JP 11228515 (English Translation attached) and WO 02/00649.

Determining the scope and contents of the prior art

US Patent NO. 6,294,532 discloses on column 32, the compound XVII which can prepare XIV (see column 31, line 5 and column 32, line 15):



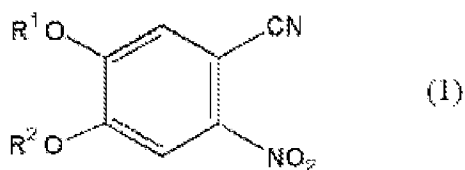
and



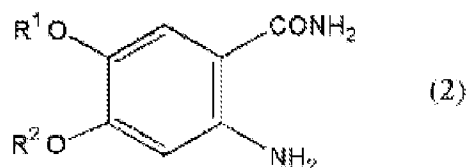
(which corresponds to applicants step

(c) and applicants' formulas V and II). When A1 is an amino group, formic acid or an equivalent can be utilized to cause cyclisation to obtain formula XIV, column 32 lines 33-48. An equivalent of formic acid is disclosed as formamide, see line 23, column 32. Preferred values for R3 and m are seen on column 7 wherein m is preferably 1 or 3 and X7 is preferably -O-; on column 10 wherein R3 is preferably R15X7; and on column 11 wherein preferred values of R15 include methyl and 3-morpholinopropyl. The compound XIV is an intermediate to prepare compounds of the formula (I) which are useful for the treatment of specific cancers, column 2.

JP 11228515 discloses the process of preparing (2) from (1):



and

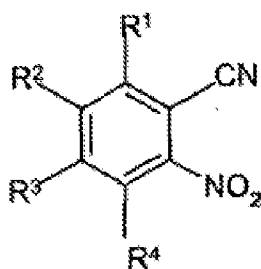


(which corresponds to applicants steps (a) and (b) and formulas III, IV and V), page 2 of translation. The preparation is useful for preparing anthranilamides useful in the

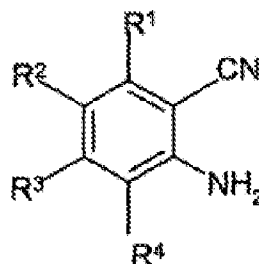
Art Unit: 1626

production of medicines (page 1). R1 and R2 can be substituted or unsubstituted alkyl, such as methyl ethyl and propyl, page 3. The process utilizes a palladium catalyst for the hydrogenation and is carried out in the presence of an alkali metal bases such as calcium carbonate in a polar protic solvent such as methanol, page 4.

WO 02/00649 discloses the process of preparing compounds of the formula (IX) with compounds of the formula (XIII), page 59 and 57:



(XIII)



(IX)

and

(which corresponds to applicants step (a)). R2 and R3 can be methoxy or 3-morpholinopropoxy, see page 78 which discloses the use of sodium hydrosulfite as a water-soluble inorganic reducing agent in the preparation of the compound H, see also page 77. Preferences for R2 and R3 are also seen wherein R2 and R3 are X1R9 wherein X1 is oxygen and R9 can be methyl or one of R2 and R3 can be –OC1-5alkylR33 wherein R33 is 3-morpholinopropoxy. The compounds of the formula IX are useful for preparing compounds of the formula (I) which are useful for the treatment of specific cancers, page 3.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that US Patent No. 6,294,532 discloses the process of preparing (XIV) from (XVII) which corresponds to step (c) of the claimed invention. US Patent No. 6,294,532 does not disclose the compounds of formulas (III) and (IV) as found in the instant claims or the process steps of (a) and (b) as in the instant claims.

The difference between the prior art of JP 11228515 and the instant claims is that JP 11228515, while disclosing a process which corresponds to steps (a) and (b) of the claimed invention, does not disclose the compound of formula (II) nor process step (c).

The difference between the prior art of WO 02/00649 and the instant claims is that WO 02/00649m while disclosing a process which corresponds to step (a) of the claimed invention, does not disclose steps (b) and (c).

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, the claimed process is no more than a selective combination of prior art teachings done in a manner obvious to one of ordinary skill in the art since each step of the process appears to be relatively complete in itself and there is no indication of an interaction between steps of such a type that would lead one of ordinary skill in the art to doubt that a substitution of alternative steps known to the art could be made. In re Mostovych, 144 USPQ 38 (1964). All of the claimed steps (a), (b) and (c) were known in the prior art and one skilled in the art could have combined the steps as claimed by known methods with no change in their

Art Unit: 1626

respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

Rebecca Anderson
Primary Examiner
Art Unit 1626, Group 1620
Technology Center 1600

11 February 2008

Application/Control Number: 10/527,461
Art Unit: 1626

Page 9